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Via UPS
Document Processing Center (7407M)
EPA East - Room 6428
(Attn: TSCA Section 8(e) Coordinator)
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004-3302

Re: TSCA Section 8(e) Submission for [redacted]

Dear Sir or Madam:

[redacted] hereby submits information to the U.S. Environmental Protection Agency (EPA) under section 8(e) of the Toxic Substances Control Act (TSCA) regarding a combined repeated dose and reproductive toxicity screening study in rats for [redacted]. This chemical substance is listed on the confidential TSCA Chemical Substances Inventory (TSCA Inventory) via premanufacture notice (PMN) [redacted]. The substance is a site-limited intermediate that is rarely if ever isolated and that is not sold commercially.

An OECD 422 screening study was undertaken in the European Union for the purpose of REACH registration. [redacted] Specifically, the Company previously has obtained results from a similar (non-OECD) reproductive toxicity screening study on a more pure sample of the chemical substance, in which no adverse effects were observed.

Although the Company has not made a determination as to whether a substantial risk of injury to human health or the environment is presented by the findings, this information is being submitted in accordance with EPA's TSCA section 8(e) guidance and requirements to discharges any section 8(e) responsibilities that might exist. [redacted]

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If you have any questions regarding this submission, please do not hesitate to contact [redacted].

Sincerely,

[redacted]

[redacted]

Enclosures: Attachment 1 - Summary of Results

Attachment 2 - CBI Substantiation (CBI)

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Attachment 1

Summary of Results

[redacted] reports the results of a combined repeated dose and reproductive toxicity screening study for [redacted] (hereinafter "the substance") administered by oral gavage to Wistar HanTM:RccHanTM:WIST strain rats. The substance is a site-limited intermediate that is rarely if ever isolated and that is not sold commercially. The screening study was carried out based on OECD Guidelines for the Testing of Chemicals No. 422.

The test sample was administered to three groups of animals, each consisting of twelve male and twelve female rats, for eight weeks (including a two week pre-pairing phase, pairing, gestation, and early lactation for females) at dose levels of 100, 300, and 1000 (reduced to 500) mg/kg bw/day. Due to a marked adverse response in the first week of treatment, the high dose group animals were removed from treatment for two days and then restarted at 500 mg/kg bw/day. Subsequently, the early termination of the high dose group was necessitated by animal welfare considerations.

Oral administration of the test substance resulted in the detection of treatment-related effects (e.g., inflammatory gastric changes) in animals of both sexes from all treatment groups, precluding classification of a No Observed Adverse Effects (NOAEL) for systemic toxicity.

In treatment groups that went on to rear offspring, no treatment-related effects were detected in the reproductive parameters for females treated at 100 or 300 mg/kg bw/day. Therefore, the NOAEL for reproductive toxicity was determined to be 300 mg/kg bw/day in female rats. In the male rats, histological changes in the male reproductive organs were observed in the 100 and 300 mg/kg bw/day treatment groups and were determined to be treatment-related. As a result, a NOAEL for reproductive toxicity in male rats could not be determined.

These findings are a significant departure from the results of a study conducted approximately six months earlier by the same laboratory, [redacted]. In [redacted], an evaluation of subchronic oral toxicity and reproductive screening of [redacted] was conducted for seventy days at dose levels of 250, 500, and 1000 mg/kg bw/day in three groups of five male Wistar HanTM:RccHanTM:WIST strain rats. Minor effects in animals were observed at all dose levels that were not considered to be

toxicologically significant and deemed be secondary to the slightly irritating or unpalatable taste of the test substance. There were no marked differences in response among the administered dose levels. The NOAEL was determined to be 1000 mg/kg bw/day for both systemic toxicity and reproductive toxicity.

The test material in [redacted] was comprised of approximately [redacted] percent of [redacted] compared to approximately [redacted] percent in [redacted]. It is theorized that the presence of a dimerized version of the substance or other impurities may be responsible for the findings in [redacted]; however, the available information is insufficient to draw a conclusion concerning the toxicological mechanism at this time.

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Attachment 2

TSCA 8(e) Substantiation of Confidentiality

(1) Is your company asserting this confidential business information (CBI) claim on its own behalf? If the answer is no, please provide company name, address and telephone number of entity asserting claim.

On its own behalf, the Company submits the following substantiation of its claims to hold the testing laboratory, the project number, the confidential chemical name and CASRN of the substance, the company name, and any other information marked as CBI confidential.

(2) For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.

The information claimed as confidential should be held confidential indefinitely, i.e., until this technology is obsolete, or until the information is widely known. As discussed below, disclosure prior to this time could result in commercial detriment to the Company.

(3) Has the information that you are claiming as confidential been disclosed to any other governmental agency, or to this Agency at any other time? Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.

The Company has not disclosed the information claimed confidential to any other U.S. agency. International notification filings have maintained the confidentiality of the same information.

(4) Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.

This information is held strictly confidential within the Company and disclosed only to outside legal counsel and government agencies who appropriately protect its confidential status. Future disclosures also will be restricted. To prevent undesired disclosure by Company employees, the Company requires that employees sign an agreement prohibiting disclosure of this and other proprietary information.

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(5) If anyone outside your company has access to any of the information claimed CBI, are they restricted by confidentiality agreement(s). If so, explain the content of the agreement(s).

The Company securely guards the information by not disclosing the specific chemical identity of the substance used for manufacture in the United States to third parties, except under non-disclosure agreements or to those who otherwise are required by law to protect the confidentiality of this information, in which confidentiality is required to be permanently maintained.

(6) Does the information claimed as confidential appear or is it referred to in any of the following: a) advertising or promotional material for the chemical substance or the resulting end product; b) material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting end product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale); c) professional or trade publications; or d) any other media or publications available to the public or to your competitors. If you answered yes to any of the above, indicate where the information appears, include copies, and explain why it should nonetheless be treated as confidential.

The information claimed as confidential does not appear in advertising or promotional materials, or other similar materials, professional or trade publications, or any other media available to the public or competitors. The substance at issue is a site-limited intermediate that is rarely if ever isolated and that is not sold commercially by the Company. The confidential chemical name and CASRN do not appear on the product MSDSs.

(7) Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, provide copies of such determinations.

No U.S. Federal agency or court has ruled on the confidentiality of this information.

(8) Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public? In your answer, explain the causal relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitors' access to your customers. Address each piece of information claimed CBI separately.

The Company has made a substantial investment in time and resources to design a less hazardous product option for the market. Disclosure of this information on the intermediate

to the final product would likely result in premature discovery of the Company's commercial plans. In addition, there would be substantial harm to the Company's competitive position due to the ability of a competitor to reverse engineer the final commercial product with this information at a substantial savings in time and resources. Currently, the information claimed as confidential cannot be ascertained without a major research effort.

(9) Has the substance been patented in the U.S. or elsewhere? Is a patent for the substance currently pending?

The Company is aware that a third party filed a patent on this substance; however, the patent was subsequently abandoned. The Company has not patented this substance. The Company has filed a patent for a molecule for which the production process uses this substance; however, the existence of a patent does not disclose that this specific product is being commercially developed over others or otherwise reveals our Company's commercial interests and intent concerning the specific substance and its derivatives.

(10) Is this substance/product commercially available and if so, for how long has it been available on the commercial market? If on the commercial market, are your competitors aware that the substance is commercially available in the U.S.? If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate how soon a market will be established. What is the substance used for and what type of product(s) does it appear in?

This substance is a site-limited intermediate that is rarely if ever isolated and that is not sold commercially by the Company. The Company is not aware that the substance is commercially available from any other supplier in the United States.

(11) Describe whether a competitor could employ reverse engineering to identically recreate the substance.

Without understanding the information claimed as confidential in this filing, reverse engineering of this substance would be difficult, requiring a major long-term research effort because the substance itself is not sold commercially. Knowledge of the chemical identity permits competitors to save research and developmental time and costs, thereby giving them an unfair advantage in entering the market and curtailing the motivation to develop new technology.

(12) Do you assert that disclosure of this information you are claiming CBI would reveal: a) confidential processes used in manufacturing the substance; b) if a mixture, the actual portions of the substance in the mixture; or c) information unrelated to the effects of the substance on human health or the environment? If your answer to any of the above questions is yes, explain how such information would be revealed.

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Disclosure of this information would reveal information currently held as confidential on the TSCA Inventory (this substance is listed on the TSCA Confidential Inventory). The substance is a site-limited intermediate that is rarely if ever isolated and that is not sold commercially. Therefore, its disclosure would reveal valuable and confidential manufacturing process information for other substances manufactured by the Company that are listed on the TSCA Confidential Inventory. Disclosure of this information would likely result in substantial harm to the Company's competitive position.

(13) Provide the Chemical Abstract Service Registry Number for the product, if known. Is your company applying for a CAS number now or in the near future? If you have applied for a CAS number, include a copy of the contract with CAS.

The Chemical Abstract Service Registry Number for this substance is [[redacted]].

(14) Is the substance or any information claimed CBI the subject of FIFRA regulation or reporting? If so, explain.

The substance or any information claimed CBI is not the subject of FIFRA regulation or reporting.